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| 09/743,840      | 01/17/2001  | Barbara A. Zilinskas | 13216-73220         | 8791             |

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EXAMINER

FOX, DAVID T

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1638

DATE MAILED: 08/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/743,840

Applicant(s)

ZILINSKAS ET AL

Examiner

David T. Fox

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 30 December 2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

5-00

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's amendments of 25 March 2005 have obviated the indefiniteness rejections.

The rejection of the claims under 35 USC 112, first paragraph, regarding new matter has been withdrawn, in view of the discovery of basis for the queried phrase on page 15 of the specification, line 19.

The oath remains objected to under 37 CFR 1.66 and 1.68, for containing non-initialed and/or non-dated alterations, as stated on page 2 of the last Office action. A new oath under 37 CFR 1.52(c) is required.

Applicant's intent to file a new oath, as stated on page 4 of the response of 25 March 2005, is acknowledged.

Applicant's arguments regarding the remaining rejections set forth in the last Office action are deemed moot, in view of the withdrawal of those rejections, in favor of the new grounds of rejection set forth below.

Claims 1-2 and 5-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to an Agrobacterium-mediated method of turfgrass transformation comprising a) culturing embryogenic turfgrass seed tissue on a medium that promotes de-differentiation to form regenerable friable turfgrass callus tissue, b) inoculating the friable turfgrass callus tissue in the presence of acetosyringone with Agrobacterium comprising a vector comprising the virB, virC and virG genes from plasmid pSB1 or pSB4, said vector further comprising a heterologous

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DNA construct and a selectable marker conferring to transformed cells resistance to a selection agent, wherein the DNA construct and selectable marker are operably linked to a promoter from a monocotyledonous species, c) co-culturing the Agrobacterium-inoculated turfgrass callus in the presence of acetosyringone in order to transform cells of the turfgrass callus, d) selecting transformed turfgrass cells by culturing the Agrobacterium-inoculated callus tissue on a selection medium comprising the selection agent, wherein the transformed cells are resistant to the selection agent and are selected by their growth in the presence of the selection agent, and e) regenerating a transformed turfgrass plant from the transformed turfgrass cells; and to transformed turfgrass plants produced by that method; does not reasonably provide enablement for claims broadly drawn to a method for transforming turfgrass tissue produced from organogenic tissue from any explant, using an Agrobacterium vector with only one or a few of the virulence genes present on pSB1 or pSB4, under acetosyringone-free conditions; or the resultant turfgrass plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to the use of any organogenic tissue from any turfgrass explant, any vir gene(s) from two super-binary plasmids, and any culture conditions to produce Agrobacterium-transformed turfgrass. In contrast, the specification only provides guidance for the obtention of Agrobacterium-transformed turfgrass when embryogenic seed tissue is used as the source of friable callus, when all three virulence genes present on either of the superbinary plasmids are present, and

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when acetosyringone is present. See page 15 of the specification, lines 15-19; page 16, lines 12-13 and lines 27-31; page 17, lines 3-9; page 21, lines 13-17; page 24, lines 9-11 and 19-34; page 25, lines 1-8; page 27, lines 25-27 and 32-34; page 28, lines 1-20; page 29, lines 26-35; page 30, lines 1-21).

Turfgrass has been particularly recalcitrant to *Agrobacterium*-mediated transformation, even when utilizing methods developed for other cereals, as admitted by Applicant on page 12 of the specification, lines 31-35. In general, monocotyledonous cereal species have been recalcitrant to transformation in general and *Agrobacterium* in particular, and have been recalcitrant to the obtention of whole transformed plants, due to lack of competence of cells for transformation and/or regeneration. See Potrykus, page 535, column 2; page 536, Figures 3 and 5; page 537, Figure 20; page 538; page 539, column 1, top two paragraphs; page 541, column 1, bottom paragraph.

Hiei et al (1997, *Plant Molecular Biology*, submitted by Applicant) teach that acetosyringone-mediated activation of *Agrobacterium*, the use of highly dividing embryogenic tissues produced from embryos (which are obtained from seeds), and the use of all of the vir genes present on super-binary vectors derived from pTiBo542 (namely the virB, virC and virG genes), were essential requirements for successful *Agrobacterium*-mediated cereal transformation (see, e.g., page 205, Abstract; page 206, column 1, bottom paragraph; page 207, column 2, bottom two paragraphs; page 209; page 210, column 2, bottom two paragraphs; page 211).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to

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obtain successful *Agrobacterium*-mediated turfgrass transformation, by developing methods involving the evaluation of a multitude of non-exemplified explants, culture conditions, and vir genes.

Claims 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhong et al, Plant Cell Reports, submitted by Applicant.

The claims are broadly drawn to transformed turfgrass plants of any species produced by an *Agrobacterium*-mediated method, comprising any transgene under the control of a monocot promoter including the rice actin promoter.

Zhong et al teach transformed turfgrass comprising a transgene comprising a beta-glucuronidase marker gene under the control of a rice actin promoter (see, e.g., page 1, Abstract). The turfgrass plants taught by the prior art would be indistinguishable from the claimed turfgrass plants, despite their alternate method of making, since the claimed method of *Agrobacterium*-mediated transformation would not confer a unique property to the resultant transformed plants.

See *In re Best*, 195 USPQ 430, 433 (CCPA 1977), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same

product produced by a different process, if the process of making the product fails to distinguish the two products.

Claims 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee, 1996, *Plant Science*, submitted by Applicant.

Lee teaches transformed turfgrass containing transgenes comprising selectable hygromycin or G48 resistance genes under the control of a rice actin promoter (see, e.g., page 3, Table 1; page 4, Table 2; page 5, paragraph bridging the columns and penultimate paragraph of column 2). See *Best* and *Thorpe* cited above.

Claims 8-9 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,948,956 (Lee et al, filed 16 October 1997).

Lee et al teach *Agrobacterium*-mediated transformed turfgrass plants comprising a rice actin promoter operably linked to an antibiotic resistance selectable marker (see, e.g., column 5, line 63 through column 6, line 5; column 6, lines 50-54; column 7, lines 14-36 and 48-50; column 10, lines 5-6; and claims 1, 3, 8, 12, 15-17). Although the plants of Lee et al were obtained via nodal transformation rather than callus transformation, the *Agrobacterium*-mediated transformed turfgrass plants taught by Lee et al would be indistinguishable from those claimed. See *Best* and *Thorpe* cited above.

Claims 1-2 and 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komari et al (1996, *The Plant Journal* 10: 165-174, Applicant submitted), in view of Christensen et al (1996, *Transgenic Research* 5: 213-218, Applicant submitted), further in view of Lee (1996, *Plant Science* 115: 1-8, Applicant submitted).

The claims are broadly drawn to a method of transforming turfgrass comprising culturing regenerable turfgrass callus, including that produced from seed, with *Agrobacterium* comprising a monocotyledon promoter (including a ubiquitin promoter) and a selectable marker gene, further comprising genes conferring agronomic traits such as disease resistance, wherein the *Agrobacterium* comprises some virulence genes present on vectors pSB1 or pSB4.

Komari et al teach the advantages of the super-binary vectors pSB1 or pSB4 comprising a hygromycin resistance gene for transforming cereal plants such as rice (see, e.g., page 165, Abstract and column 2, first full paragraph; page 166, Figure 1; page 167, column 2, penultimate paragraph). Komari et al also teach the advantages of *Agrobacterium*-mediated transformation in terms of efficiency and discrete transfer of large pieces of DNA, and suggest the wide applicability of their technique (see, e.g., page 165, column 2, top paragraph; page 172, column 2, first full paragraph, last sentence).

Komari et al do not teach turfgrass transformation or the use of the maize ubiquitin promoter or rice actin promoter.

Christensen et al teach the advantages of a highly expressed corn ubiquitin promoter for expression of selectable marker genes in rice, wheat and maize (see, e.g., page 213, paragraph bridging the columns; page 217, column 1, top paragraph).

Lee teaches the desirability of turfgrass transformation for conferring agronomic traits such as disease resistance, wherein mature seeds were used to produce transformable embryogenic callus, and wherein transformants contained selectable



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antibiotic resistance genes under the control of a rice actin promoter (see, e.g., page 2, column 1, paragraphs 1, 3 and 4; page 5, paragraph bridging the columns and penultimate paragraph of column 2).

It would have been obvious to one of ordinary skill in the art to utilize the method of Agrobacterium-mediated cereal transformation taught by Komari et al, and to modify that method by incorporating the monocot promoters taught by Christensen et al and Lee et al to transform turfgrass, as suggested by Komari et al and Lee. Choice of agronomic gene would have been the optimization of process parameters.

Amendment of claim 1 to overcome the rejection under 35 USC 112, first paragraph, and the cancellation of claim 7, would obviate the obviousness rejection.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 5, 2005

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180-1638

A handwritten signature in black ink, appearing to read "David T. Fox", is written over the printed name and group number.